

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

**KERRY LANGSTAFF, et al**

Petitioners,

v.

**ALLEN A. MITCHELL, M.D.,  
SAMUEL M. LESKO, M.D., and  
TRUSTEES OF BOSTON UNIVERSITY**

Respondents.

§ Civil Action No. 04-MBD-10128-GAO  
§ and No. 04-MBD-10137-GAO

§ Related Civil Action:  
§ United States District Court for the  
§ Northern District of California, San  
§ Jose Division  
§ Civil Action No. 03-CV-01116  
§ KERRY LANGSTAFF, et al vs.  
§ MCNEIL CONSUMER &  
§ SPECIALITY  
§ PHARMACEUTICALS, et al  
§  
§

**PETITIONERS' LANGSTAFF PLAINTIFFS**  
**MOTION FOR RECONSIDERATION**

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, Petitioners, by and through their attorney of record, and files this Memorandum in Support of Petitioners' Langstaff Plaintiffs ("Langstaff Plaintiffs") Motion for Reconsideration. Langstaff Plaintiffs bring forth this Motion for Reconsideration from the Order of the Court entered on June 29, 2004 ("Order") denying Langstaff Plaintiffs Motion to Compel and granting Respondents Mitchell, Lesko, and Trustees of Boston University (collectively "Boston University") Motion to Quash Deposition Subpoenas and Subpoenas Duces Tecum. Langstaff Plaintiffs seek relief to allow for oral depositions of Drs. Mitchell and Lesko and for production of documents from subpoenas duces tecum.<sup>1</sup>

**I. BACKGROUND**

The underlying litigation is a pharmaceutical products liability case involving the injury and untimely death of 8-year-old Kaitlyn Sierra Langstaff from Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN) caused by an adverse reaction to Children's Motrin.

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<sup>1</sup> Langstaff Plaintiffs hereby incorporate and adopt all prior briefings filed with the Court for purposes of this Motion for Reconsideration.

Defendants McNeil Consumer & Speciality Pharmaceuticals (“McNeil”) and Johnson & Johnson relied upon the results from the Boston University Fever Study to support the approval of the over the counter marketing of Children's Motrin. This study was the critical safety study that McNeil used to claim the safety of ibuprofen in the treatment of fever in children in the U.S. This litigation is ongoing in the United States District Court for the Northern District of California.

Langstaff Plaintiffs served subpoenas duces tecum upon the Custodian of Records for Dr. Allen A. Mitchell and the Custodian of Records for Slone Epidemiology Center (“Slone”) of Boston University. Both custodians are affiliated with and represented by Boston University. Langstaff Plaintiffs also served subpoenas for oral deposition and duces tecum on Drs. Allen Mitchell and Samuel Lesko, employees of the Slone Epidemiology Center<sup>2</sup> at Boston University during the time of the Boston University Fever Study, to be deposed on May 26 and 27, 2004. As these subpoenas sought discovery from nonparties, they were issued from this Court. Boston University objected to Langstaff Plaintiffs subpoenas duces tecum to which Langstaff Plaintiffs filed their Motion to Compel. Boston University also moved to quash the subpoenas for oral deposition and the subpoena duces tecum. On June 10, 2004 the Court held a hearing on these related motions. After the hearing, the Court ordered that Langstaff Plaintiffs Motion to Compel denied in its entirety and Boston University's Motion to Quash granted in its entirety. *See* Memorandum and Order dated June 25, 2004 and entered on June 29, 2004. Langstaff Plaintiffs now bring this Motion for Reconsideration to notify of error in the Court's order as Langstaff Plaintiffs are entitled to such crucial discovery, and Langstaff Plaintiffs also present to the Court additional evidence not previously available when the hearing in this matter was held, which also verifies that Langstaff Plaintiffs are entitled to the discovery sought from Boston University.<sup>3</sup>

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<sup>2</sup> Dr. Mitchell is the Director of the Slone Epidemiology Center. Dr. Lesko was the senior investigator until 2000.

<sup>3</sup> Due to vital nature of discovery sought from Boston University, Langstaff Plaintiffs have moved to extend the discovery deadline in the underlying litigation.

## II. STANDARD

A Motion for Reconsideration is not explicit in the Federal Rules of Civil Procedure. *Van Skiver v. United States*, 952 F.2d 1241, 1243 (10<sup>th</sup> Cir. 1991); *In re Pabon Rodriguez*, 233 B.R. 212, 218-19 (Bankr. D. Puerto Rico 1999). The federal courts have consistently stated that a motion so denominated is either a motion “to alter or amend” under Rule 59 or a motion for “relief from judgment” under Rule 60(b). *Accord Computerized Thermal Imaging, Inc. v. Bloomberg, L.P.*, 312 F.3d 1292, 1296 n.3 (10<sup>th</sup> Cir. 2002); *Pabon Rodriguez*, 233 B.R. at 219 (citing *In re Wedgestone Financial*, 152 B.R. 786, 788 (Bankr. D. Mass. 1993)). The rules are distinct, serving different purposes with different consequences, but the determination of which rule applies depends essentially on when the motion is served. *Pabon Rodriguez*, 233 B.R. at 219 (citing *Van Skiver*, 952 F.2d at 1243). If a motion is served within ten days of the rendition of judgment, then it falls under Rule 59.<sup>4</sup> *Pabon Rodriguez*, 233 B.R. at 219; see Fed. R. Civ. P. 59(e); *Bloomberg*, 312 F.3d at 1296 n.3; *Jones v. UNUM Life Ins. Co. of America*, 223 F.3d 130, 136 (2<sup>nd</sup> Cir. 2000). Langstaff Plaintiffs Motion complies with Fed. R. Civ. P. 6(a), as it is made within ten days of entry<sup>5</sup> of the Court’s order, excluding weekends and holidays, thus it should be construed as being made pursuant to Rule 59. *Jones*, 223 F.3d at 136; *Pabon Rodriguez*, 233 B.R. at 219; see *Aybar v. Crispin-Reyes*, 118 F.3d 10, 14 n.3 (1<sup>st</sup> Cir. 1997) (citing *Skagerberg v. State of Oklahoma*, 797 F.2d 881, 883 (10<sup>th</sup> Cir. 1986)). The Order issued by this Court is considered final, as it ends the litigation in this Court on the merits, therefore it constitutes a “judgment” under Rule 59. See *Quackenbush v. Allstate Ins. Co.*, 517 U.S. 706, 712 (1996); *Cusumano v. Microsoft Corp.*, 162 F.3d 708, 712 (1<sup>st</sup> Cir. 1998).

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<sup>4</sup> Relief from Judgment or Order under Rule 60(b) includes motions evaluating newly discovered evidence, which by due diligence, could not have been discovered in time to move under Rule 59. See Fed. R. Civ. P. 60(b). A motion for reconsideration filed past the ten-day time constraint of Rule 59 is then construed as being made under Rule 60(b), which allows for a party to move within one year. *Id.*; see *In re Aguiar*, \_\_\_ B.R. \_\_\_ n.9, 2004 WL 1427057 \*4 n.9, (1<sup>st</sup> Cir. 2004); *Bloomberg*, 312 F.3d at 1296 n.3.

<sup>5</sup> The time period for this Motion began when the order was entered on June 29, 2004. *Lopez v. Corporacion Azucarera de Puerto Rico*, 938 F.2d 1510, 1514 n.9 (1<sup>st</sup> Cir. 1990); see Fed. R. App. P. 4(a).

A judgment may be altered or amended if the party seeking reconsideration shows at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.<sup>6</sup> See *Kabacinski v. Bostrom Seating, Inc.*, 98 Fed. Appx. 78, 81 (3<sup>rd</sup> Cir. 2004); *Nat'l Metal Finishing Co., Inc. v. BarclaysAmerican/Commercial, Inc.*, 899 F.2d 119, 124 n.2 (1<sup>st</sup> Cir. 1990); *McLaughlin v. Unum Life Ins. Co. of America*, 212 F.R.D. 40, 41 (D. Me. 2002). Rule 59 is not intended for presentation of arguments, which could have been presented previously. See *Aybar*, 118 F.3d at 16. A motion brought to amend or alter under Rule 59(e) may properly be invoked to request a district court to reconsider, vacate, or even reverse its prior holding. *Ortiz v. Gaston County Dyeing Machine Co.*, 277 F.3d 594, 597 n.1 (1<sup>st</sup> Cir. 2002) (citing *Nat'l Metal Finishing Co.*, 899 F.2d at 123-24 (citations omitted)). The purpose of a Rule 59(e) motion is to allow the court to reevaluate the basis for its decision. *Keyes v. National R.R. Passenger Corp.*, 766 F. Supp. 277, 280 (E.D. Pa. 1991); *In re Dove*, 199 B.R. 342, 344 (Bankr. E.D. Va. 1996).

Rule 59(e) motions for reconsideration are appropriate when the court has made an error in interpreting facts or law or when there has been a significant change in the law or facts since the submission of the issue to the court. *Keyes*, 766 F. Supp. at 280; *Dove*, 199 B.R. at 344. The successful motion for reconsideration shows that there were facts or legal issues properly presented but overlooked by the court in its decision. *Blue Mountain Mushroom Co., Inc. v. Monterey Mushroom, Inc.*, 246 F.Supp.2d 394, 398-99 (E.D. Pa. 2002). Possible examples of valid motions for reconsideration could include situations where the court has misunderstood a

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<sup>6</sup> Although these grounds are widely observed, Langstaff Plaintiffs would note that they were formulated and used on appeals from decisions determining the suit in its entirety, i.e. summary judgment. Accordingly, Langstaff Plaintiffs note that such a threshold should be relaxed in pre-trial determinations regarding discovery as no determination on the merits of the suit would have been made by the trial court. Discovery challenges deserve a more liberal analysis to correspond with the broad discovery capabilities of the Federal Rules of Civil Procedure. Langstaff Plaintiffs contend that if Boston University met its initial burden under Rule 45, then substantial need is met via a showing of relevance and exclusivity and/or uniqueness of the discovery sought from Boston University. See *infra*.

party, or has made a decision outside of the adversarial issues presented to the court by the parties, or has made an error not of reasoning, but of apprehension. *Assoc. for Disabled Americans, Inc. v. Amoco Oil Co.*, 211 F.R.D. 457, 477 (S.D. Fla. 2002). The district court has considerable discretion to alter its prior ruling. *See Nat'l Metal Finishing Co.*, 899 F.2d at 124-26.

### III. RECONSIDERATION OF COURT'S ORDER

#### A. Summary of Court's Order

In its Order, the Court found Drs. Mitchell and Lesko to be unretained experts whom fall under Rule 45 protection. The Court determined that Rule 45's language governing disclosure of an unretained expert's "opinion or information" deserved broad application to cover testimony on assumptions, decisions, processes, and protocols involved in scientific research. *See* Order at 5-6. The Court read Fed. R. Civ. P. 45 in conjunction with Fed. R. Evid. 702 in determining what would constitute expert evidence. *Id.* at 6. Although, the Court noted that Rule 45(c)(3)(B)(ii) offers no protection to discovery sought that does not inquire into the expertise of the unretained expert. *Id.*

The Court found that Langstaff Plaintiffs had failed to show the "substantial need" necessary to justify discovery of protected expert evidence. *Id.* at 8. The Court then reasoned that there was no efficient manner to separate the protected expert evidence from the non-protected non-expert evidence. *Id.* at 10. This rationale for granting Boston University's Motion to Quash was also found applicable to deny Langstaff Plaintiffs Motion to Compel. *Id.* at 11.

#### B. Rule 45

Rule 45 of the Federal Rules of Civil Procedure establishes the same broad scope of discovery to a non-party that exists to the parties involved in the litigation. *United States ex rel. Schwartz v. TRW, Inc.*, 211 F.R.D. 388, 392 (C.D. Cal. 2002). Rule 45(d) adopts the standards

set out in Rule 26(b)(1), which permits discovery of any non-privileged matter relevant to the subject matter even if it would be inadmissible at trial, so long as it would appear reasonably calculated to lead to the discovery of admissible evidence. *Anker v. G.D. Searle & Co.*, 126 F.R.D. 515, 518 (M.D.N.C. 1989). Relevance for discovery purposes is given very broad meaning. *Allen v. Howmedica Leibinger, Inc.*, 190 F.R.D. 518, 521 (W.D. Tenn. 1999). If relevance is in doubt, the district court is to be permissive. *Truswal Systems Corp. v. Hydro-Air Engineering, Inc.*, 813 F.2d 1207, 1212 (Fed. Cir. 1987); *Compaq Computer Corp. v. Packard Bell Electronics, Inc.*, 163 F.R.D. 329, 335 (N.D. Cal. 1995). “Courts, whose only connection with the controversy is to rule on discovery motions for the case which is pending in another district, should be cautious in restricting discovery because such ‘ancillary’ courts will find it more difficult to have a complete understanding of the case and what is relevant and, therefore, should err on the side of permitting discovery.” *Anker*, 126 F.R.D. at 518 (*citing Truswal*, 813 F.2d at 1211-12; *Heat and Control, Inc. v. Hester Industries, Inc.*, 785 F.2d 1017, 1024 (Fed. Cir. 1986)).

A basic premise in American jurisprudence is that the court has the right to evidence from every individual unless protected by constitutional, statutory, or common law privileges. *Branzburg v Hayes*, 408 U.S. 665, 688 (1972). No general academic privilege protects research from discovery. *Burka v. U.S. Dept. of Health and Human Services*, 87 F.3d 508, 521 (C.A.D.C. 1996) (citations omitted). The weight of federal authority and case law holds that a non-party, involuntary expert or non-fact witness does not have a right to decline to give testimony or produce documents even though the witness will be compelled to divulge matters which are normally considered confidential, sensitive, proprietary, or which pertain to his expertise or special skill. *Anker*, 126 F.R.D. at 520, (*citing Truswal Systems Corp.*, 813 F.2d 1207; *Heat and Control, Inc.*, 785 F.2d 1017; *Deitchman*, 740 F.2d 556; *Kaufman v. Edelstein*, 539 F.2d 811; and Annotation, *Expert Testimony Refusal*, 50 A.L.R. 4th 680 (1986)). A Court should only not honor a subpoena if “it is palpable that the evidence sought can have no possible bearing upon the

issues.” *See Hercules Powder Co. v. Rohm & Hass Co.*, 3 F.R.D. 302, 304 (D. Del. 1943). To quash or modify a subpoena requires the party seeking such relief to meet “the heavy burden of establishing that compliance with the subpoena would be ‘unreasonable and oppressive.’” *Hussey v. State Farm Lloyds Ins. Co.*, 216 F.R.D. 591, 596 (E.D. Tex. 2003). Langstaff Plaintiffs have exhausted discovery from McNeil in the underlying litigation, which has consequently, and repeatedly, directed Langstaff Plaintiffs to Boston University as the source of the relevant discovery sought.

### C. New Evidence

On June 7, 2004, the transcript of the deposition of Dr. Anthony Temple was completed. *See* Deposition of Dr. Anthony Temple at 582, attached and incorporated as Exhibit A. Dr. Temple was deposed in the underlying litigation. He is employed by McNeil as Vice President of Medical Affairs, and he was a primary liaison to Drs. Mitchell and Lesko and the Boston University Fever Study (“BUFS”) while it was being conducted. *See* Exhibit A at 12, 20, 26. On June 16, 2004, Michael (Rusty) Nicar, Langstaff Plaintiff’s toxicology expert, completed his report. *See* Nicar Report, attached and incorporated as Exhibit H. The recent formulation of the Temple deposition and Nicar report, along with additional evidence produced, which is noted and attached accordingly, stresses the relevance and substantial need of Langstaff Plaintiffs to be able to execute the subpoenas issued.

Dr. Temple’s testimony consisted of a number of inconsistencies regarding the organization of the BUFS. Dr. Temple testified that Slone determined the objects of primary interest in the BUFS. *See* Exhibit A at 366. However, he also testified that the final protocol for the BUFS was a mutual decision between Boston University and McNeil. *Id.* at 368. Langstaff Plaintiffs need to know if McNeil exhibited control over the structure of BUFS, including the reporting of adverse drug effects, specifically dealing with skin reactions. Dr. Temple’s contradictory testimony indicates that such control existed and was exercised by McNeil. This

evidence imparts directly on the possible bias in the study and/or is a statement against interest, such that discovery to Boston University is necessary.

McNeil was eager to get the study completed. *Id.* at 451. Slone sent progress reports to McNeil. *Id.* at 472-73. Yet, Temple is unaware as to why Slone would send progress reports. *Id.* at 472. Langstaff Plaintiffs need to know if McNeil exercised pressure or provided incentives in order to accelerate the completion of BUFS. Particularly, when the exact incidences of adverse drug reactions were unknown, and the goal of BUFS was to determine such risks. *See* BUFS Advisory Committee Minutes of 11-27-90, attached and incorporated as Exhibit C. Although, McNeil was aware of many risks associated with ibuprofen in 1984, and opposed a competitor's application to make available over-the-counter. *See* Exhibits M, N, O. McNeil, apparently, has a differing opinion now, even though the evidence of ibuprofen-related adverse skin effects is increasing. *See* Exhibit H at 11. Langstaff Plaintiffs need to know the knowledge that Slone passed along to McNeil.

Dr. Temple does not recall being present during discussions by the advisory committee as to whether a case was EM, SJS, or scalded-skin syndrome, although he recalls being present when the data was presented. *Id.* at 479. Dr. Temple did not recall whether he expressed any opinions on whether a reaction was associated with a drug. *Id.* at 375. However, Dr. Temple knew that the data on four cases of EM was presented to the advisory committee for BUFS. *Id.* at 63. Dr. Temple testified that Mitchell and Lesko did not accept the four reported hospitalizations due to EM to be casually related to ibuprofen. *Id.* at 219. Although, Mitchell and Lesko think that they might be related to ibuprofen. *Id.* at 224-25. Incidences of EM in BUFS were significant enough to require further evaluation, which was done by Slone. The results from Slone determined that McNeil did not do any additional research. *Id.* at 217. Temple cannot answer as to which data became available, which caused the committee to remove a case from the table of EM cases. *Id.* at 484. Langstaff Plaintiffs need to query Drs. Mitchell and Lesko to clarify how cases of patients suffering from EM were treated, whether Dr. Temple or another



individual was present on behalf of McNeil, and if McNeil provided input into decisions. Langstaff Plaintiffs must also inquire as to what further evaluation was done by Slone regarding the number of incidences of EM in the BUFS study and what knowledge was imparted to McNeil.

McNeil was aware of reports in 1983 of SJS and TEN being associated with ibuprofen. *Id.* at 76; *See* Ibuprofen Review, attached and incorporated as Exhibit L. Temple testified that Slone went through the data listings that revealed two cases of SJS. *Id.* at 229. However, Temple testified that these cases were not brought to the attention of the advisory committee. *Id.* at 230, 234. McNeil was required to report all serious drug reactions during clinical trials. *Id.* at 236. Temple testified that McNeil had no data on the SJS cases. *Id.* at 240-41. The BUFS had no cases of SJS or TEN, according to Dr. Temple. *Id.* at 432. Although, the data listings prove otherwise. *See* Exhibit G. Temple testified that Slone provided the data listings to McNeil years after the study was concluded. *See* Exhibit A at 237. Langstaff Plaintiffs need to inquire from Boston University if the SJS cases were reported to McNeil and the FDA during the time of the study.

Temple does not remember the details of the FDA submission of the BUFS study, but Slone directly provided to the FDA in “some ways.” *Id.* at 239. McNeil had the right, which it exercised, to review the JAMA article from the BUFS before it was final. McNeil also had the right to recommend changes. Dr. Temple cannot recall if any changes were recommended. *Id.* at 243. Although there were two reports of SJS in the BUFS data listings, they were not reported in the JAMA article. *See* Deposition of Dr. Edward Nelson, attached and incorporated as Exhibit F; JAMA Assessment, attached and incorporated as Exhibit K. Langstaff Plaintiffs require deposition of Mitchell and Lesko as they would know if McNeil recommended changes to the JAMA article.

There were 499 adverse clinical events not requiring hospitalization in the study. *See* Exhibit A at 464. Three EM and 105 rash cases were included. *Id.* at 464. The JAMA article

only reported cases requiring hospitalization. *Id.* at 467. Thus, the medical community was unaware of three unreported EM's. *Id.* Temple testifies that Mitchell and Lesko did not report the data of non-hospitalized cases to the FDA. *Id.* at 468. But, he then testifies that he doesn't know whether it was reported or not. *Id.* at 472. Langstaff Plaintiffs need to know the incidences that were excluded from the reports and if this knowledge was reported to the FDA.

Dr. Lesko was allowed to break the blind (to discover the drug being used with a participant) in some cases. *Id.* at 416. Although, the only appropriate study design was double blind according to Mitchell. *See* Exhibit C. Lesko broke the double blind study six months later with no complaints from Mitchell or the Advisory Committee. *See* BUFS Advisory Committee Minutes of 5-31-91, attached and incorporated as Exhibit I. According to the New Drug Application Mitchell and the Advisory Committee were kept blind. *See* Exhibit J. Temple testified that the report to the FDA stated that Lesko was potentially aware of the study drug received by participants, but Temple doesn't know when or if that happened, as he stated, "You'd have to ask him how many he actually looked at. It was probably a handful." *See* Exhibit A at 418. The purpose of keeping principal investigators blinded is to ensure that the study accurately reports the adverse drug reactions without bias. *Id.* at 421. Temple says that if the FDA asked McNeil to check the National Death Index, then McNeil would have asked Slone to do such, and he is not aware if Slone did or not. *Id.* at 449-50. Langstaff Plaintiffs must know if Lesko broke, and if so, when and for what reasons. Langstaff Plaintiffs also must inquire as to McNeil's awareness and/or participation.

Dr. Temple testified that Slone considered all data, whether it was considered a primary interest or not. *Id.* at 369. Dr. Temple has an understanding of how Drs. Mitchell and Lesko determined which relative risks to report in the JAMA article, but "they would have to answer specifically." *Id.* at 438. Dr. Temple's understanding of the relative risks was not part of the JAMA article. *Id.* at 438-39. Temple defers to Mitchell and Lesko for evaluation of the study in terms of associating a reaction to the drug. *Id.* at 444-45. He is aware that there were patients

lost to follow up, but he does not know the number. *Id.* at 445. Temple, as the McNeil representative, directs Langstaff Plaintiffs to Boston University as the source for answers.

Only Slone knows why the determination was made to collect hospital records, but not emergency room records, although Temple agrees that emergency room visits would be the type of adverse drug reaction relevant to an evaluation of an OTC drug. *Id.* at 456-58. Temple refers Langstaff Plaintiffs to Slone for an explanation of why 110 out of 113 of discharge diagnoses from hospitals were found to be unrelated to ibuprofen. *Id.* at 461. In the 113 hospitalizations, there was one case of EM, two of Kawasaki disease, and one of conjunctivitis. *Id.* at 460. McNeil denies any participation in making the determination of which reactions were related to the drug. *Id.* at 462. TEN can be diagnosed as Kawasaki disease or scalded-skin syndrome. *Id.* at 481. In the case that was categorized as scalded-skin syndrome, and not TEN, Temple states that Slone would be the source to discover if lab tests were done to differentiate between them. *Id.* at 481. Slone obviously was aware of TEN as one its members published a paper on the study of TEN. *See* Kaufman, Epidemiologic Approaches to the Study of Toxic Epidermal Necrolysis, attached and incorporated herein as Exhibit D. All cases of TEN are caused by drug reactions, and it is more common in females. *See* Exhibit H at 3.

Temple states that BUFS was about making an assessment of whether a relationship exists between rare events as a background with other drugs and other events. *See* Exhibit A at 509. Mitchell and Lesko did a number of additional analyses to the data over the years with some being unpublished. *Id.* at 502-03. However, McNeil never received any reports to Temple's knowledge. Temple is not aware if they studied the synergistic interaction between viral illnesses and skin reactions or any adverse reaction. *Id.* at 502. Langstaff Plaintiffs require the unpublished reports and to know whether they were sent to McNeil, particularly if there were skin reaction studies.

Temple believes there was some attempt by Slone to determine if the treating physician attributed the condition to the study medication. *Id.* at 464-45. As many skin-related diseases,

including SJS, EM, and others did not become published in the JAMA article, *see* Exhibits K, and P-S, or possibly get reported to the FDA, Langstaff Plaintiffs seek to discover the participating physicians in BUFS in order to gain knowledge into what information Slone sought and if the physicians were given input regarding adverse skin reactions which were found by Slone to not be ibuprofen related. It is well established that ibuprofen carries a risk of serious adverse skin reactions. *See* Exhibit H at 4, 10. The BUFS study did not provide information on less severe side effects that did not require hospitalization. *Id.* at 8. Nor did the subsequent study by Mitchell and Lesko on febrile patients. *Id.* at 9.

Dr. Temple did not recall the contract price for the study, but did know it was “several million dollars.” *Id.* at 376. Langstaff Plaintiffs should be entitled to this information as it goes directly to bias, particularly if McNeil is still paying.

Efficacy was a predominant variable in the BUFS study. *See* Exhibit H at 13. The dose given to one-third of the patients was sub-therapeutic as it was lower than the current recommended dose on the OTC label. *Id.* This is not an appropriate means to conduct a safety study. *Id.* The interim findings during BUFS showed more frequent adverse skin-related side effects than expected. Although the skin reactions were three times more frequent than asthma, of which Motrin already warns, Lesko published on asthma in BUFS. The publication was sponsored by McNeil. *Id.* at 15. Langstaff Plaintiffs need to know if McNeil is still directing research, and if skin reactions have been studied or are not being studied.

#### **D. Boston University’s Motion to Quash**

The Court found that Drs. Mitchell and Lesko are unretained experts through reference to Rule 26, as they have not been retained to act as experts for McNeil in the underlying litigation. *See* Order at 4-5. Langstaff Plaintiffs argued that the protections of Rule 45(c)(3)(B)(ii) would not apply as the BUFS study was conducted at the request of McNeil. Notwithstanding this argument, Langstaff Plaintiffs have demonstrated a substantial need for the testimony and

materials that cannot be otherwise met. *See* Fed. R. Civ. P. 45(c)(3)(B)(iii). The Court noted the advisory committee's notes regarding Rule 45(c)(3)(B) was intended to protect the intellectual property of experts. *See* Order at 4; Fed. R. Civ. P. 45 advisory committee notes, 1991 amend. This entails the ability to "withhold their expertise." *Id.* However, this ability is not absolute, as it only applies until the party opposing the quash makes the showing required for a conditional denial by making "assurance of reasonable compensation." *See* Fed. R. Civ. P. 45 advisory committee notes, 1991 amend. Langstaff Plaintiffs have made this assurance, at the hearing, that Drs. Mitchell and Lesko would be reasonably compensated for their time. *See* Fed. R. Civ. P. 45(c)(3)(B)(iii). Langstaff Plaintiffs agreed to abide by the Court's determination of whether this fee would be under the "reasonable" standard of Rule 26(b)(4)(C)(i) or the statutory witness fee of 28 U.S.C. § 1821 as courts have split on this determination. *See Demar v. United States*, 199 F.R.D. 617, 618-19 (N.D. Ill. 2001).

The *Kaufman* Court created a non-exclusive list of factors for the trial court to consider in determining whether to compel the testimony of a non-party expert. *Kaufman v. Edelstein*, 539 F.2d 811, 822 (2d Cir. 1976). The factors listed were "the degree to which the expert is being called because of his knowledge of facts relevant to the case rather than in order to give opinion testimony; the difference between testifying to a previously formed or expressed opinion and forming a new one; the possibility that, for other reasons, the witness is a unique expert; the extent to which the calling party is able to show the unlikelihood that any comparable witness will willingly testify; the degree to which the witness is able to show that he has been oppressed by having continually to testify." *Id.*

The key factor is that Drs. Mitchell and Lesko are unique witnesses. As the individuals who conducted and controlled the study, requested by Defendant McNeil, which was the basis for FDA approval for over the counter use of ibuprofen for children, Drs. Mitchell and Lesko are the only source to answer Respondents questions regarding the Boston University Fever Study. *See id.* at 821; *In re Cary*, 167 B.R. 163, 167 (Bankr. W.D. Mo. 1994). They know the facts

regarding the research and analysis of skin-related reactions, as Dr. Temple repeatedly deflects questions to them. They would be testifying about the research that they already performed and formed opinions. They possess insight that was not relayed in any published text. And they have not been oppressed as they have never testified before, and there is no indication of a deluge of subpoenas. The discrepancies present, in the attached exhibits, can only be addressed by those who conducted the research. The *Kaufman* factors weigh in favor of Respondents.

**E. Langstaff Plaintiffs Motion to Compel**

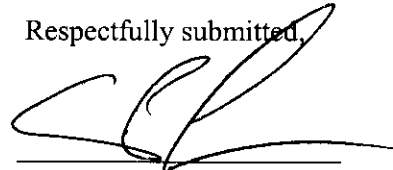
A party may obtain documents from a nonparty by subpoena. Fed. R. Civ. P. 34(c) and 45(a)(1)(c). The nonparty may serve objections to inspection or copying of any or all of the designated items within 14 days of service of the subpoena. Fed. R. Civ. P. 45(c)(2)(B). The Court excused Boston University's noncompliance with the time requirement referencing the general notice imparted on Langstaff Plaintiffs that Boston University objected to production. *See* Order at 11. However, Langstaff Plaintiffs were not aware as to which duces tecum requests that Boston University would object. Rule 45(c)(2)(B) requires the recipient of a subpoena to raise all objections at once, not in intervals, so that discovery does not become a "game." *In re DG Acquisition Co.*, 151 F.3d 75, 81 (2<sup>nd</sup> Cir. 1998).

#### IV. CONCLUSION

Langstaff Plaintiffs bring this Motion for Reconsideration as they are entitled to discovery from nonparties, such as Boston University, and they have documented a substantial need to overcome any burden inflicted Respondents. *See* Fed. R. Civ. P. 34(c) and 45(a)(1)(C). Accordingly, Petitioners Motion for Reconsideration should be granted, and the Court should reverse or modify its prior Order to allow for Langstaff Plaintiffs to depose Mitchell and Lesko and receive the documentation they seek.

**WHEREFORE, PREMISES CONSIDERED,** Petitioners respectfully request this Court grant Petitioners Motion for Reconsideration and grant Petitioners any and all other relief to which they may be justly entitled.

Respectfully submitted,



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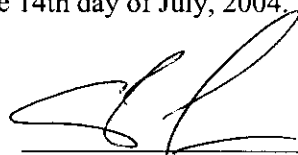
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**ATTORNEYS FOR PETITIONER**


**CERTIFICATE OF SERVICE**

I certify that the foregoing Motion for Reconsideration was served on Boston University via hand delivery and all counsel of record via facsimile 14th day of July, 2004.

  
\_\_\_\_\_  
Edward Paul Coady

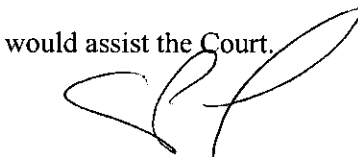
**CERTIFICATE OF CONFERENCE**

I certify that counsel for Petitioners has left messages with counsel for Respondents, whom is expected to contest this Motion.

  
\_\_\_\_\_  
Edward Paul Coady

**REQUEST FOR ORAL ARGUMENT**

I certify that Petitioners wish to be heard by the Court regarding this matter as expeditiously as possible and believe that oral argument would assist the Court.

  
\_\_\_\_\_  
Edward Paul Coady